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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/648,844

08/25/2003

Subramaniam C. Krishnan

30909-1

3856

24256 7590 11/04/2008  
DINSMORE & SHOHL, LLP  
1900 CHEMED CENTER  
255 EAST FIFTH STREET  
CINCINNATI, OH 45202

EXAMINER

MALAMUD, DEBORAH LESLIE

ART UNIT

PAPER NUMBER

3766

MAIL DATE

DELIVERY MODE

11/04/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/648,844	<b>Applicant(s)</b> KRISHNAN, SUBRAMANIAM C.	
	<b>Examiner</b> DEBORAH MALAMUD	<b>Art Unit</b> 3766	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10/6/08.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 18,21,36 and 37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 18,21,36 and 37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 March 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/12/08</u> .   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

2. The Examiner acknowledges the amendments received 06 October 2008. Claims 1-17, 19-20 and 22-35 are cancelled; claims 18, 21 and 36-37 are pending.

### ***Claim Objections***

3. In view of the amendments received 06 October 2008, the objection to the claims is withdrawn.

### ***Response to Arguments***

4. Applicant's arguments, see "Remarks," filed 06 October 2008, with respect to the rejection(s) of claim(s) 18, 21 and 36-37 under Eigler as disclosing two electrodes on the catheter, have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Eigler et al (U.S. 6,328,699) and Svenson.

### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 18, 21 and 36-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Svenson et al (U.S. 5,409,008) in view of Eigler et al (U.S. 6,328,699) (both cited in previous actions). Regarding claims 18, 21 and 36, Svenson discloses (col. 2, lines 30-36) “a mapping catheter which includes a polymer member, bipolar sensing electrodes placed on a distal end of said polymer member, a spaced unipolar electrode at a spaced distance from said bipolar electrodes, and a lumen within said polymer member for the passage of a laser catheter or other instrument.” Svenson further discloses, (col. 3, lines 13-17) “a laser delivery catheter can be passed through the center hollow lumen of the mapping catheter and the myocardium irradiated for a predetermined period of time to ablate the site.” The examiner considers this to be a hollow lumen, a first electrode positioned on a distal end of the catheter, and a second electrode spaced proximally from the first electrode and positioned on the catheter. Svenson further discloses (col. 3, lines 53-64; Figure 1) “mapping catheter (10) including the catheter tip (12), the stainless steel support tube (14), the hand piece (16), and the Y-connector (18). The hand piece joins the Y-connector and the stainless steel support tube together and includes the electrical junction (20) of the wires (21a-21c) with electrical connectors (22a-22c), which in this example are insulated alligator clips. A polymer tube-like sheath (24) connects between the catheter tip (12) and the hand piece, and houses a plurality of wires (21a-21c) between the polymer sheath and the underlying stainless steel support tube.” The examiner considers this to be a hollow sheath having a distal end. It is to be noted that the functional language and

introductory statement of intended use of claims 21 and 36, have been carefully considered but are not considered to impart any further structural limitations over the prior art. Since Svenson utilizes a mapping catheter as claimed by the applicant, Svenson is therefore capable of being inserted into a sheath (such as polymer sheath 24), having a needle urged through, and being used as a dilator for performing a transseptal puncture and locating the fossa ovalis, on the basis of the claimed parameters. In addition nothing prevents the catheter of Svenson from being performing these functions. Therefore, they are capable of locating and penetrating the fossa ovalis and being used with a sheath and a needle.

7. Svenson further discloses, (col. 2, lines 56-62) "The current catheter provides a tool for more accurately mapping the electric potential of very small areas of the inner chambers of the heart. In addition, the catheter provides a way to simultaneously obtain the QRS and EKG signals, thus providing a method to more rapidly and accurately identify the focus or foci of the tachycardia." The examiner considers this system therefore inherently to include a recording device for recording electrograms, the recording device in electrical communication with the electrodes of the catheter. In the alternative, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a recording device for recording electrograms in order to display the data gathered by the electrodes for future diagnosis.

8. Svenson discloses the claimed invention except for a transseptal needle and sensors of electrophysical activity of an interatrial septum. Eigler however discloses (col. 3, lines 30-65; col. 4, lines 1-22; Figure 1) a system for accessing the left atrium

“from the right atrium through the atrial septum separating the right and left atria. The flexible lead (10) and pressure transducer (15) will be anchored to the atrial septum.” A “Brockenbrough catheter and needle are used to pierce the atrial septum for access to the left atrium.” Figure 1 depicts the system, which includes “a Brockenbrough catheter (20) inside a peel-away sheath (22), with a flexible guidewire residing within the Brockenbrough catheter.” With the access assembly (18) in place within the right atrium (30), “the Brockenbrough catheter is used to pierce the atrial septum (41) by extending the Brockenbrough needle (not shown) through the atrial septum into the left atrium (36). In the figures, the atrial septum has been pierced by the needle, the catheter advanced over the needle, and the needle withdrawn from the catheter leaving the catheter in place inside the left atrium.” The system (col. 7, lines 65-67; col. 1-8) includes “one or more additional sensors (75) configured to monitor pressure at a location outside the left atrium, or a different physical parameter inside the left atrium or elsewhere. For each sensor, a sensor lead (77 and 80) conveys signals from the sensor to a monitoring unit (82) disposed inside the housing of the unit. It should also be noted that the sensor lead connecting the pressure transducer to the monitoring apparatus might also be combined with or run parallel to another lead such as an electrical EKG sensor lead or a cardiac pacing lead, either of which might be placed in or near the left atrium.”

9. Eigler and Svenson both disclose implantable methods and apparatus for detecting signals in the heart in order to diagnose and treat a patient. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was

made to modify Svenson's mapping electrodes with Eigler's transseptal needle and puncture system in order to provide a minimally-invasive technique for gathering interatrial septum data for more accurate patient diagnosis.

10. Further regarding claim 36, Eigler discloses (col. 3, lines 54-57) placement of the lead and sensor "with the aid of visualization techniques including standard fluoroscopy, cardiac ultrasound, or other appropriate visualization techniques used alone or in combination.

11. Regarding claim 37, Svenson and Eigler disclose the claimed invention except for an interelectrode separation of between about 2 mm and about 4 mm. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide an interelectrode separation of this length, since it has been held that discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. Furthermore, Svenson and Eigler disclose the claimed invention but does not disclose expressly the tapered end of a catheter. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the catheter tip shape as taught by Eigler, with the tapered end as claimed, because the applicant has not disclosed the tapered end provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the applicant's invention to perform equally well with the catheter tip shape as taught by Eigler and Svenson, because it is used to pierce the interatrial septum for atrial placement as required by the claim. Therefore, it would have

been an obvious matter of design choice to modify Svenson and Eigler to obtain the invention as specified in the claims.

### ***Conclusion***

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DEBORAH MALAMUD whose telephone number is (571)272-2106. The examiner can normally be reached on Monday-Friday, 9.00am-5.30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Carl H. Layno/  
Supervisory Patent Examiner, Art Unit 3766

/Deborah L. Malamud/  
Examiner, Art Unit 3766